# GOVERNMENT OF INDIA
# HEALTH AND FAMILY WELFARE
# LOK SABHA

STARRED QUESTION NO:354
ANSWERED ON:17.04.2002
GMP NORMS OF WHO ON SMALL PHARMACEUITCAL MANUFACTURES
SANJAY PASWAN

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

(a) whether the Indian Pharmaceutical Alliance has requested the Government to impose Good Manufacturing Practices (GMP) norms of WHO on Small Scale Pharmaceutical Companies;

(b) if so, the reasons put forth by the Indian Pharmaceutical Alliance for the same and the Government`s reaction thereto; and

(c) the steps being taken by the Government to safeguard the interest of Small Scale Pharmaceutical Companies?

## Answer

MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR)

(a)to(c) A statement is laid on the table of the Lok Sabha.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 354 FOR 17.4.2002

(a)&(b): The need for upgrading the requirements for Good Manufacturing Practices (GMPs) have been expressed at various fora in recent years in order to ensure availability of quality drugs. However, no specific request from Indian Pharmaceutical Alliance to impose GMPs on small scale drugs manufacturers was received.The National Human Rights Commission in their order dated 31.3.99 and Pharmaceutical Research and Development Committee headed by Dr. R.A. Mashelkar, D.G., CSIR in its report o November, 99 stressed the need for upgradation of GMPs to that of International standards.Accordingly, Schedule M to the Drugs and Cosmetics Rules 1945 was amended vide GSR No. 894 (E) dated 11.12.2001.

(c) The amended provisions are required to be implemented uniformly by all drug manufacturers. However, following steps have been taken to safeguard the interest of small manufacturers:-

(i) In order to give the existing manufacturing units time for making improvement, the upgraded GMPs shall become applicable after a period of 2 years from the date of notification.

(ii) Majority of modifications incorporated under revised Schedule relate to in-house validations, documentation, preparation of Standard Operating Procedures (SOPs) and training of staff which require no substantial expenditure.

(iii) Workshops are also proposed to be conducted to educate small scale manufacturers on salient features of GMP and its compliance.